

Will FASTER Move Us Into an Allergen-Free Future?

FOOD PROTECTION CONNECTION

The Implications of the Food Allergy Safety, Treatment, Education, and Research Act of 2020



The National Institute of Allergy and Infectious Diseases (NIAID) defines food allergy as an “adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food.”

Food allergy and food intolerance are often confused or mistaken for one and the same, yet they are very different. Food allergy is immune-mediated, while food intolerance is non-immune mediated. Food allergy is a pathological, potentially deadly immune reaction triggered by normally innocuous food protein antigens. Every protein has the potential to be allergenic from a strictly biological standpoint, but it’s not the case in reality. Food allergies can be broadly classified into those that are IgE mediated, those that are mediated by both IgE-

dependent and IgE-independent pathways (mixed), and those that are not IgE mediated. IgE-mediated food allergies are the class of food allergy associated with the risk of severe or fatal reactions.

Allergenic foods have been identified as a food safety hazard and affect millions of consumers. People with life-threatening food allergies are considered disabled under the Americans with Disabilities Act (ADA) Amendments Act of 2008 in the United States and are protected accordingly. With the increasing knowledge about biological and clinical characteristics of food allergy, collective efforts from the food industry, governments, clinicians, and food scientists have been made to protect sensitive consumers.



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According to the Center for Food Safety and Applied Nutrition (CFSAN),

As originally enacted in 1938, section 403(i) of the Federal Food, Drug, and Cosmetic (FDC) Act required that the label of a food that is fabricated from two or more ingredients declare each ingredient by its common or usual name (except that spices, flavorings, and colors could be declared as a class). Although ingredient declarations complying with section 403(i) provide some information to food allergic consumers, in some cases, the common or usual name of an ingredient may be unfamiliar to consumers and many consumers do not recognize that certain ingredients contain or are derived from a food allergen. This situation led, at least in part, to the enactment of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Pub. L. 108-282).

FALCPA is an amendment to the Federal FDC Act and requires that the label of a food that contains an

they represent the foods most likely to result in severe or life-threatening reactions.

FALCPA requires food manufacturers to label food products that contain an ingredient that is or contains protein from a major food allergen in one of two ways to make it easier for allergic consumers to identify and avoid these foods containing major allergens:

The first option for food manufacturers is to include the name of the food source in parentheses following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement.



THE FOOD ALLERGY SAFETY, TREATMENT, EDUCATION, AND RESEARCH (FASTER) ACT

was signed into law by President Biden in April 2021. FASTER requires greater priority be given to food allergy research by the federal government, as well as making *sesame* the ninth major food for which the FDA will require plain language labeling.

ingredient that is, or contains protein from, a “major food allergen” declare the presence of the allergen in the manner described by the law. Congress passed FALCPA to make it easier for food allergic consumers and their caregivers to identify and avoid foods that contain major food allergens.

FALCPA identifies eight foods or food groups as the major food allergens. They are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. The eight major food allergens identified by FALCPA accounted for 90 percent of all documented food allergies in the U.S. at the time of its passing, and

The second option is to place the word “Contains” followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in type size that is no smaller than the type size used for the list of ingredients.

Continued on page 22

'FASTER ACT' PROMOTES MORE FOOD ALLERGY RESEARCH

The Food Allergy Safety, Treatment, Education, and Research (FASTER) Act H.R. 1202, S. 578 was signed into law by President Joseph R. Biden on April 23, 2021. FASTER requires greater priority be given to food allergy research by the federal government, as well as making *sesame* the ninth major food for which the Food and Drug Administration (FDA) will require plain language labeling beginning January 1, 2023. This is the first new allergen that has been added to FALCPA since 2006.

According to Allergome database, 2,554 allergen sources have been described as allergenic as of May 12, 2021 and more than 160 foods have been identified to cause food allergies in sensitive individuals. An estimated 85 million Americans are affected by food allergies and intolerances, with 32 million of those people suffering from life threatening allergies and 1.5 million allergic to sesame. Every three minutes someone in the U.S. seeks emergency medical treatment for a food allergy reaction.

There is only one FDA-approved treatment for food allergies and it is only for peanut allergies. In 2020, the FDA approved Palforzia

[Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] to mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. There is no cure for food allergies.

Food allergy is both common and costly, yet currently the federal government spends just 19 cents per person on food allergy research. The passage of FASTER establishes a risk-based scientific process and framework for establishing additional allergens covered by FALCPA, and requires Health and Human Services (HHS) and the Secretary of Health to report on scientific opportunities in food allergy research that examines prevention, treatment, and potential cures as well as allergen prevalence, testing, and risk management. This federal reporting required by FASTER is a major step towards improving the health and quality of life for those living with food allergies.

Strict avoidance is still the only effective measure to prevent the occurrence of food allergies, therefore appropriate labeling is considered the critical risk management tool in the food industry. Regulations surrounding food allergen labeling vary greatly from country to country globally with emphasis placed on specific food allergen prevalence within a country which can be influenced by a

NOT ALL BIOCHEMICAL CHARACTERISTICS

involved in food allergen pathogenesis are currently known, and the complete understanding of disease mechanism lies at the forefront of food allergy research.



variety of factors, including cultural differences and dietary habits—to name a few.

Not all biochemical characteristics involved in food allergen pathogenesis are currently known, and the complete understanding of disease mechanism lies at the forefront of food allergy research. There is great variation in the likelihood of specific foods provoking allergic sensitization. Various studies are being conducted to determine characteristics of proteins that make them more prone to being an allergen,

and surrounding factors in determining the allergenicity potential. Technological advances in instrumentation have enabled unprecedented discoveries in the signaling pathways underlying immune tolerance, sensitization and desensitization to food allergens, including the roles of allergen-specific cells in the largely unknown etiologies of food protein-induced reactions.

Defining the major allergenic and antigenic components of immunoresponsive proteins is driving research in allergenic



responses. Through whole genome sequencing (WGS) researchers are working to discover immunostimulatory pathways/regions of allergenic proteins to develop products with attributes that are more favorable to individuals with food allergies.

In light of the prevalence and costs of food allergy, effective prevention and treatment methods would be of substantive value, both economically and clinically. The current standard of care for food allergens is avoidance and the treatment of systemic reactions with adrenaline, usually in the form of an Epi-Pen.

With the passage of FASTER, increased focus and resources are being devoted to research on risk factors and proactive preventive measures to mitigate the increasing prevalence of food allergies. This includes advances in research, development of new therapies, and gaining complete understanding of mechanisms of disease involved in food allergy.

Previously, avoidance of common food allergens during pregnancy and breastfeeding was standard guidance; however, evidence now suggests that early exposure—including maternal consumption to potential food allergens—may decrease the risk of developing common food allergens in infants.

Furthermore, the introduction of an increased diversity of foods during infancy may be associated with a reduced risk of allergic disease development. The Learning Early About Peanut Allergy (LEAP) trial indicated that the early initiation of peanut consumption may prevent peanut allergy. The findings of this landmark study resulted in published guidance recommending the early introduction of peanuts to high-risk infants secondary to the potential association between delaying peanut introduction and an increased risk of peanut allergy. There is preliminary evidence that the early introduction of allergenic foods may prove to be a promising prevention strategy for food allergy, and strict avoidance is no longer recommended.

The role of the gut microbiota in immune system development related to food allergen tolerance is another

active area of research on the horizon. Although causality has not been established, the correlation has been observed semi-consistently and researchers hold out promise for advances through this connection.

Another interesting study has looked at whether high serum Vitamin D levels are inversely associated with risk of food allergy due to Vitamin D being an immunomodulator, and its interaction with immune cells involved with food protein antigens as a potential for further investigation.

Separately, a therapy being explored is the development of monoclonal antibodies as therapeutic agents to target and help block the processes of allergic reaction specific to IgE binding, resulting in faster and safer desensitization of individuals.

Additionally, an interesting area of research is preventive

allergy immunizations with DNA and mRNA vaccines, where the encoded proteins are transcribed, translated, and presented to the immune system eliciting powerful T-cell responses. The immunity induced by this type of vaccine closely resembles responses of non-allergic individuals and could provide long-term protection from food allergy.

SUMMARY

Food allergens is a topic of global importance due to its impact on public health. While there are no cures for food allergies and current treatment still relies on strict avoidance, the goal and the challenge are creating a future where the millions of Americans who have life-threatening immune responses can live safely with improved quality of life through the development of effective treatments, and ultimately a cure for food allergies. **E**

RESOURCES AND REFERENCES

- www.allergome.org
- *Allergy & Asthma Network*. <https://allergyasthmanetwork.org/>
- *Food Allergy Research & Education (FARE)*. <https://www.foodallergy.org/>
- *Food allergy: immune mechanisms, diagnosis and immunotherapy (nih.gov)*
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6283005/>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097586/>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5123910/pdf/nihms-828091.pdf>
- <https://www.sciencedirect.com/science/article/abs/pii/S0273230012000797>
- *The Americans with Disabilities Act Amendments Act of 2008 | U.S. Equal Employment Opportunity Commission (eoc.gov)*
- *U.S. Food and Drug Administration (FDA)*. <https://www.fda.gov/food>

SAN CE Questions | FOOD PROTECTION CONNECTION



This Level III article assumes that the reader has a thorough knowledge of the topic. The desired outcome is to integrate analysis and application of knowledge, incorporating continuous quality improvement into best practice.

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- The FASTER Act added _____ as the ninth major food allergen.
 - Sulfites
 - Sesame
 - Cultured meat
- Food allergies are considered a disability, but individuals with food allergies are not covered under ADA.
 - True
 - False
- Adrenaline administered through an Epi-pen is the cure for a life-threatening allergic reaction.
 - True
 - False
- Which is *not* a potential advancement in allergens currently being researched?
 - Vaccines
 - Monoclonal antibodies
 - Injecting allergenic proteins into fetuses
- There is preliminary evidence that the early introduction of allergenic foods may prove to be a promising prevention strategy for food allergy, and strict avoidance is no longer recommended. What is the name of the trial that produced the results on which this recommendation is based?
 - LEAP
 - FALCPA
 - LEAN
- Which of the following is *not* a classification of food allergies?
 - Non-IgE mediated
 - mRNA dependent
 - IgE mediated
- What differentiates a food allergy from a food intolerance?
 - Food intolerance is immune mediated
 - Food allergy is non-immune mediated
 - Food allergy is immune mediated

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